

Office Description: The Office of Special Health Issues (OSHI) coordinates and integrates the policy/program, scientific, and public health issues related to AIDS, cancer, other special health issues, and the MedWatch program. OSHI is also responsible for engaging with and communicating to health professionals, patients and patient advocates, and other special interest populations about FDA regulatory decisions and policies.

Office Activities:

The “FDA Updates for Health Care Professionals” E-list provides recent announcements particularly related to safety, medical product approvals, opportunities to comment on proposed rules, upcoming public meetings, and other information of interest to health professionals. The health professional webpage at <http://www.fda.gov/healthprofessionals> serves as a portal for FDA information, particularly safety-related information, of interest to health professionals.

The MedWatch website www.fda.gov/medwatch has been operational since 1996, and is a major outreach tool for FDA medical product safety information. MedWatch pages rank among the top ten most accessed pages on the FDA site. The page also features the popular MedWatch RSS news feed, so users can have new information delivered immediately to their computers. The MedWatch E-list broadcasts timely new safety information to both healthcare professionals and their patients. MedWatch information includes early communications about emerging safety issues, alerts about new prescribing information, Class I recalls, market withdrawals, and public health advisories for human medical products. MedWatch partner organizations disseminate these safety alerts to their members.

The HIV/AIDS program delivers timely, targeted updates to the HIV/AIDS E-list. Updates included FDA HIV/AIDS related information about product approvals, significant labeling changes, safety warnings, notices of upcoming public meetings and alerts to proposed regulatory guidances for comment.

OSHI has an interagency agreement with HRSA’s Office of Pharmacy Affairs, to collaborate with the American Association of Colleges of Pharmacy. The collaboration will assess and evaluate the science of safety curriculum within the U.S. Colleges of Pharmacy.

OSHI/MedWatch staff involves patient and health professional stakeholders in agency's participatory activities to address public health issues related to the review of new medical products and related therapies. For example, our office facilitates and/or organizes patient and health professional stakeholder telephone conferences/meetings on topics such as Sentinel, HFA albuterol transition, ESAs, HIV/AIDS. We have a Patient Representatives/Consultants program representing a variety of serious and life-threatening diseases to participate in Advisory Committee meetings to review/discuss products/issues.

Expectation: As a student completing a pharmacy rotation with the Office of Special Health Issues/MedWatch, you will be expected to attend lecture series scheduled with various offices of the FDA as well as external organizations. For successful completion of the rotation, you will be responsible for an assigned project and present the results of the project during the last week of your rotation.